PGS-123T.M.

PULSED-GALVANIC STIMULATOR

Instruction Manual

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INTRODUCTION

The Pulsed-Galvanic Stimulator is a High Voltage Galvanic system.

This device is battery powered and generates small pulses of electrical current. The output signal has a "twin-peak monophasic wave form with a fixed duration". Each pulse is much shorter in duration (5 us) and can achieve much higher voltage than conventional stimulator.

The Pulsed-Galvanic stimulator system provides single channel in a single device package.

The polarity switch sets the polarity of the active in relation to the dispersive electrode. The active electrode is the pad that delivers the treatment current. The dispersive electrode completes the patient circuit.

The Pulsed-Galvanic stimulator has fully adjustable amplitude (voltage) and the rate of twin pulses is adjustable from 2 pairs (two pulses) per second to 100 pairs per second.

The LED indicator can show the battery condition and function mode. When turn on the power, the LED will turn into green color. If the battery power is low, the LED will show red color. In the alternation mode, the LED will alternate between red and green color.

All the selectors, controls, and switches are very clearly. The user is easy to operate this device by following the user manual.

The following warnings and precautions apply to using the Pulsed-Galvanic stimulator system:

1) Federal law (USA) restricts this device to be used by or on the order of a physician.
2) Keep this system out of children.
3) Do Not use this device on the patients who have circulatory impairment.
4) Do not stimulate over the carotid sinus.
5) Do not use this device on the patients who have demand on pacemaker.
6) Do not use this system on the pregnant women.
7) Do not use this system across the temporal region.
8) Do not apply to individuals prone to seizure.
9) Do not apply electrode over skin defects.
10) Do not apply this device transcerebrally.
11) Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.

12) Several spasm of the laryngeal and pharyngeal muscle may occur when the electrodes are placed across the neck or the mouth. This may be strong enough to close off the airway or cause difficulty in breathing.
13) Patient should never operate potentially dangerous machinery such as power saw, automobiles during treatment period.
14) Some patient may have skin irritation.

Precautions

Precautions should be observed:

1) When there is a tendency to hemorrhage following acute trauma or fracture.
2) Following recent surgical procedures when muscle contraction may disrupt the healing process.
3) When stimulating over the menstruating uterus. Where sensory nerve damage is present resulting in a loss of normal skin sensation.

Additional precautions

1) Avoid adjusting controls while operating machinery or vehicle.
2) Turn the system off before applying or removing electrodes.
3) Do not immerse the stimulator in the water or other liquid.
4) Do not use the stimulator on any muscle or for any purpose other than that for which it was prescribed.
5) Do not use the device on any individuals other than those for whom the device has been prescribed.
6) Stimulations over areas where bone is near the skin can be painful in some patients. Be sure to adjust amplitude slowly.
7) If treatment is ineffective or uncomfortable, discontinue therapy and consult your physician or therapist.
8) For external use only.
9) Do not use over the eyelids.

Adverse Reactions:

Possible allergic reaction to tape or gel. Possible skin irritation under electrode. If skin irritation persists, discontinue use and consult a physician.

TECHNICAL SPECIFICATIONS

Power : 9 volt battery or Adaptor

Output : Single channel

Output Voltage : 0-240V Max. (Single channel, load 500 Ohm) 0-350V Max. (Open circuit)

Pulse Rate : 2-100 Hz

Waveform : Positive or negative wave form.

Output Mode : Synchronous or Alternation. Alternation mode-LED alternates between green and red color.

Power : Green color LED-power on. Red color LED-low battery.

Pulse Duration : 5 us.

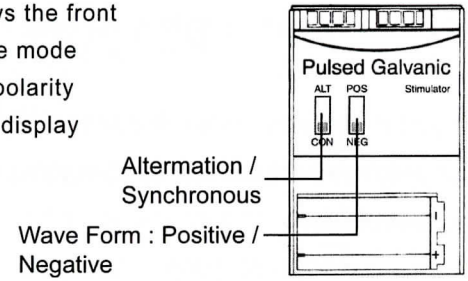
IntraPulse Interval : 100 us.

Tolerance :+/- 20%

CONTROLS AND INDICATIONS

This section describes the related switch on Pulsed-Galvanic stimulator system.

Figure 1 shows the front side oftors, the mode (left) and the polarity (right), on the display board.



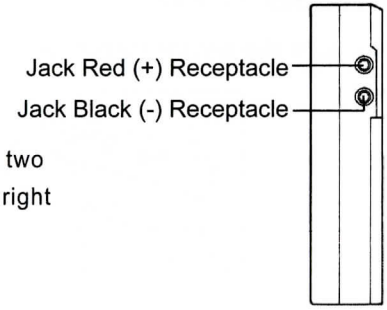
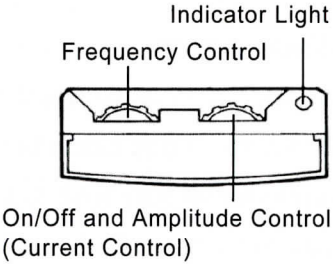


Figure 2 there are two jacks locate in the right side view.

Figure 3 shows the frequency control, the amplitude control, and an LED indicator.



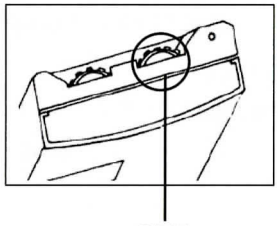
INSTRUCTIONS OF OPERATION

This section explains how to operate the Pulsed-Galvanic stimulator. This single channel device is easy to understand. The following procedure will ensure a safe and comfortable treatment.

If you receive no pain relief, consult your clinician for electrode placement or stimulation mode alternatives.

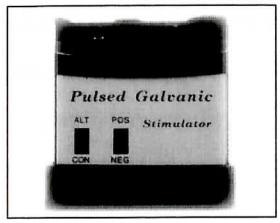
Power off

Make sure the power switch is in the OFF position.



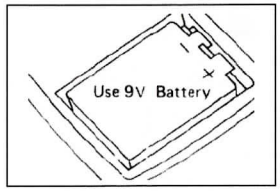
Slide cover

A slide-on panel covers the buttons controlling Modulations and Compliance timer. Your medical professional may wish to set these controls for you and request that you leave the cover in place.



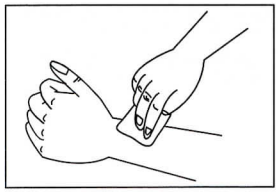
Using the 9VDC battery

Replace the battery compartment cover and press to close. Insert the battery into the compartment. If a battery is being used, match the battery terminals " + " and " - " to the label in the battery compartmt.



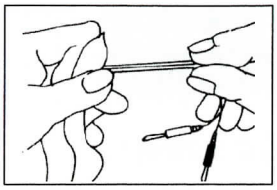
Skin preparation

The treatment site should be carefully examined and cleaned. An alcohol wipe is recommended.

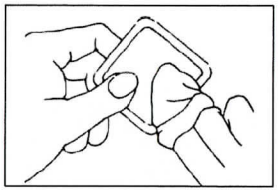


Electrode preparation

1) Clean the electrode application sites.



2) Apply gel in an even layer (about as thick as a match book cover) to the bottom of the electrode. Avoid using excessive amount of gel.

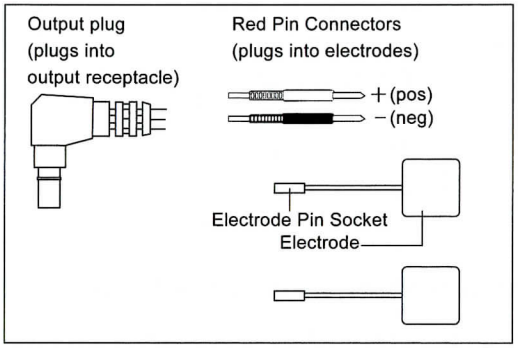


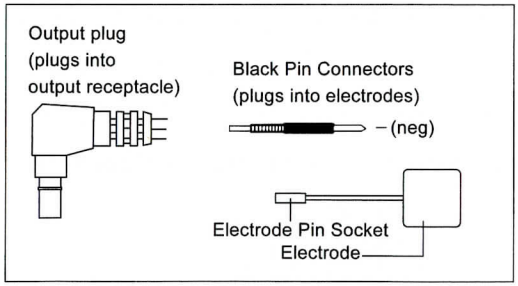
3) The electrode attached with adhesive tape. Be sure that all sides are evenly taped and that the electrode is held firmly against the skin.

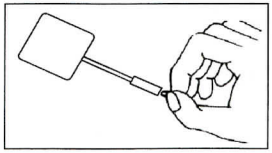
Remark: If you use the self-stick electrodes, then you can skip step 2 and step 3.

Connect leadwires and electrodes

Insert each pin of the lead wire into the female receptacle of each electrode. The red and black tipped leads should be inserted into the electrodes and the black tipped leads should be inserted into the electrode.

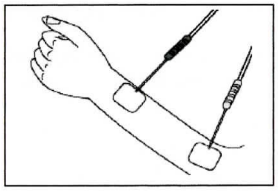






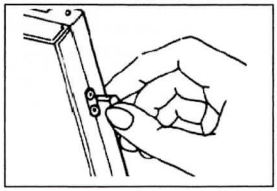
Electrode placement

Attached active electrode directly over the treatment site. Attached the dispersive pad proximal. Position the electrodes where directed by your doctor or therapist. Press the electrodes firmly in place, applying pressure from the center out to the edges to ensue good contact.



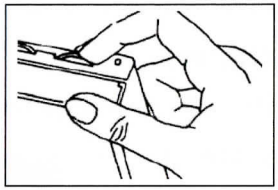
Connect leadwires and main unit

The wires provided with the system insert into the jack sockets located on right side of the device. Holding the insulated portion of the connector, push the red plug end of the wire into the red jack, black plug end of the wire into the black jack.



Power switch and Intensity control

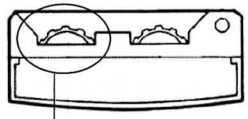
Turn " ON/OFF and Amplitude control " knob top of unit. If the control is in the OFF position, the device is switched Off. By turning the control clockwise, the power will be switched On. The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise. To reduce the current strength or switch the device Off, turn the control counter clockwise to the required setting or OFF position, respectively. Turn the power on. LED will be on (green color).



Setting the Pulse rate

Set the pulse rate as directed by the clinician. Pulse rate is adjustable. Turn " Frequency control " knob top of unit. This controls determine how

many electrical impulses are applied through the skin every second. By turning the control clockwise, the number of current impulses per second (Hz) for channel can be continually adjusted. Unless otherwise instructed, turn the pulse rate control to the 2-100 Hz range.

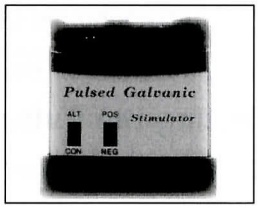


Frequency Control

Setting the Polarity and Function Mode

Select the desired polarity and function mode as directed by the clinician.

Adjustable the Alternating/Synchronous, Positive/ Negative of Mode setting.



POS means positive wave.

NEG means negative wave.

ALT means Alternation (Alternation mode-LED alternates between green and red color).

CON means Synchronous.

Set all dails and slowly turn up the amplitude until you reach the amount of stimulation recommended by the clinician. The duration of treatment should base on the recommendation of the clinician.

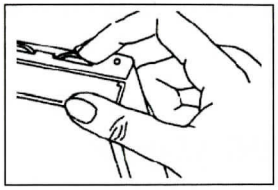
Using the 9VDC adaptor

If you use 9VDC adaptor as power supply, please follow the steps below.

1) Turn off your stimulator first. Make sure the stimulator power is OFF. Both intensity knobs are set to "OFF".
2) Take the 9V battery out of stimulator. Make sure to take out 9V battery before you use the 9VDC adaptor, otherwise the battery may explode or leak.
3) Insert the 9VDC output plug of adaptor into the 9VDC input receptacle of stimulator.
4) Put the adaptor body into the receptacle of AC outlet.
5) Then follow the indication of PREPARATION FOR USE.

Turn OFF the intensity control

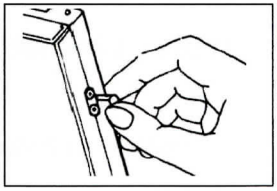
Turn the Frequency control in anticlockwise to OFF when the treatment has been completed..



Removing wire and electrode

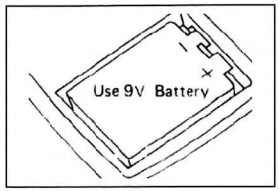
Pull out the wires from the output jacks. Leave the electrode on skin if another treatment is going to start in minutes. After a treatment session is finished, take off the electrode and clean your skin.

Note : The self-adhesive electrode is disposable. To use repeatedly, please flush the electrode mildly and leave it air-dried with the gel side up, then stick back to the paster.



Uninstall battery

Slide away the battery cover and take out the battery.



Main unit

Your Pulsed-Galvanic Stimulator device may be cleaned by wiping gently with a damp cloth moistened with a mild soapy solution. Never immerse the unit or allow it to be splashed with water or other liquids. Wipe lead wires with a damp cloth, as above, if they become soiled.

Electrode and leadwire

Reusable electrodes lose their conductive properties after repeated uses. They should be replaced when they no longer conduct properly or if the gel begins to separate from the rest of the electrode. Reusable electrodes should be stored on their protective release liner and in their resealable bags between uses.

Replacement electrodes, lead wires and batteries should be ordered through your authorized stimulation device dealer. Use only replacement parts recommended by the manufacturer. Other brands of components may cause less than satisfactory performance and/or system failure.

Battery power indication

When the battery indicator become red, it means the battery should be replaced with a new one as soon as possible. However, unit will continue to operate for several more hours before replacement.

TROUBLESHOOTING

If your Pulsed-Galvanic stimulator device seems to work improperly, use the following guide to determine what may be wrong.

1) If the LED is off, check the battery condition, or replace battery with a new one.
2) Are electrodes in proper position?
3) Check lead wires. Make sure all connectors are firmly seated.
4) Replace cord set with another to check for broken wires.
5) Check the electrode condition. Following the electrode manufacture's instructions to check electrode.

SERVICE

To obtain service, first calls your nearest dealer for assistance. You may need to send your complete Pulsed-Galvanic stimulator system with a letter describing the problems.

WARRANTY

We warrant each Pulsed-Galvanic stimulator system only (excluding lead wires, electrodes, and battery) for ONE (1) year from defects in materials and workmanship.

This warranty covers parts and labor for ONE (1) year. Thereafter until the warranty expires, only the defective part will be repaired or replaced and the customer will have to pay for the labor.

This warranty does not cover abuse, accident, damage resulting from failure to follow operating instructions and alteration/disassembly other than by us.

The defective unit must be returned to us postage prepaid and insured.

We shall not be liable for any direct or indirect consequential damages resulting from the use of the unit.

Manufacturer: Skylark Device & Systems Co., Ltd
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Guishan Township, Taoyuan County 333, Taiwan

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